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MD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,539	05/21/99	SCHUMACHER J	69430

IM22/0121

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EXAMINER	
BEISNER, W	
ART UNIT	**PAPER NUMBER**
1744	7

DATE MAILED: 01/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/316,539	SCHUMACHER ET AL.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *21 May 1999 and 04 November 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *28-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-47,50-52,54-60,63,65-73,76 and 78-80* is/are rejected.

7)☐ Claim(s) *28, 48, 49, 53, 61, 62, 64, 74, 75 and 77* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☒ received in Application No. (Series Code / Serial Number) *08/793,833* .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/793,833, filed on 18 Feb. 1997.

Information Disclosure Statement

2. The information disclosure statement filed 04 Nov. 1999 has been considered and made of record.

Specification

3. The disclosure is objected to because of the following informalities:

The reference to the parent application at the first line should read – This application is a continuation of U.S. Application No. 08/793,833, filed February 18, 1997, now U.S. Patent No. 5,935,846, which was the National Stage of International Application No. PCT/DE96/01087, filed June 19, 1996.--.

Appropriate correction is required.

Claim Objections

4. Claim 28 is objected to because of the following informalities: Claim 28 depends from canceled claim 1. This claim will not be examined on its merits since it appears that this claim should have been canceled along with claims 1-27 in the preliminary amendment dated 04 Nov. 1999. Appropriate correction is required.

5. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 28-79 have been renumbered as claims 29-80.

Note the preliminary amendment filed 21 May 1999 included new claim 28.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 37, 40, 43, 50, 54, 56, 63, 67, 69, 76 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37, 50, 63 and 76 are indefinite because it cannot be clearly determined how the recited "measuring device" structurally cooperates with the rest of the positively recited structure or method steps.

Claims 40, 54, 67 and 80 are indefinite because it cannot be clearly determined how the recited "computer control system" structurally cooperates with the rest of the positively recited structure or method steps.

In claims 43 and 69, should the language recite –relative to the amount of enzyme inhibitor—rather than "relative to the amount of enzymes"?

In claim 56, should the language recite –relative to the amount of enzyme—rather than "relative to the amount of inhibitor"?

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 29-34, 38, 55-60 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Showa Denko Kabushiki Kaisha (EP 0 329 190) in view of Koohmaraie et al.(J. Anim. Sci.).

The reference of Showa discloses a device for detecting the activity of enzymes which includes a sample treatment column, 6; a valve/pump arrangement, 1 and 2, in series with the column, 6; a test vessel, 4; temperature control structure, 3; and a detector, 5, which can be a fluoimeter (See column 7, lines 10-24). Column, 6, is capable of being used repeatedly and/or is capable of being exchanged.

The reference of Showa does not specifically recite that column, 6, can specifically remove enzyme inhibitors which correspond to the enzyme to be measured.

The reference of Koohmaraie et al. discloses that it is known in the art to measure the activity of a specific enzyme in a sample wherein the sample is first contacted with a column of Sepharose so as to remove inhibitors of the enzyme to be detected.

As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to perform the method of Koohmaraie et al. for the known and expected result of providing a system recognized in the art for performing the method of the reference of Koohmaraie et al. since both references are drawn to the detection of enzyme activities wherein the sample is first treated to remove an inhibitor substance.

12. Claims 42-47, 51, 68-73 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Showa Denko Kabushiki Kaisha (EP 0 329 190) in view of Koohmaraie et al.(J. Anim. Sci.) and further in view of Fujii et al.(US 4,030,977).

The combination of Showa and Koohmaraie et al. has been discussed above.

The above claims further differ by reciting that enzyme inhibitors rather than enzyme activities is being determined by using a column to remove enzymes rather than inhibitors.

The reference of Fujii et al. discloses that it is known in the art to purify and/or determine an enzyme or enzyme inhibitor from a fluid sample. The reference discloses

that one skilled in the art knows the specific column materials to employ to bind an enzyme or enzyme inhibitor.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the primary reference to determine enzyme inhibitor rather than enzyme activity as suggested by the reference of Fujii et al. In view of this teaching, one of ordinary skill in the art would employ a column for binding enzyme rather than inhibitor when using the system of the modified primary reference for detecting inhibitor rather than enzyme activity.

13. Claims 39, 40, 53, 54, 66, 67, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Showa Denko Kabushiki Kaisha (EP 0 329 190) in view of Koohmaraie et al.(J. Anim. Sci.) alone or further in view of Fujii et al.(US 4,030,977) and each combination taken further in view of Stevens (US 4,762,617).

The combination of Showa and Koohmaraie et al. has been discussed above. Also, the combination of Showa, Koohmaraie et al. and Fujii et al. has been discussed above.

The claims further differ by reciting that the sample and buffer are alternatively supplied to the column and that the system is automatically controlled by a computer device.

The reference of Stevens discloses a system for introducing a sample into a separation column wherein the buffer and sample are alternatively supplied and the system is controlled by a computer device.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to automate the operation of the systems of the primary reference by using a computer control system. With respect to the sample supply, use of a sample supply system as disclosed by the reference of Stevens would have been obvious for the known and expected result of providing a means recognized in the art for automating the addition of a plurality of different samples to the detection system.

Allowable Subject Matter

14. Claims 35, 36, 41, 48, 49, 53, 61, 62, 64, 74, 75 and 77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 37, 50, 63 and 76 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter:

The above claims would be allowable because the prior art of record fails to teach or fairly suggest the claimed combination of elements which includes I) a control device connected within the system so as to check the purity of the buffer discharged from the column or II) a means for measuring the degree of dilution of the discharged sample caused by the buffer of the column or III) a switching valve provided within the system such that sample can alternatively pass through the column or bypass the column in order to get to the detector device.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 29-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No.

5,935,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 29-41 are broader in scope than claims 1-33 of the patent. The instant claims employ the transitional language "comprising" which is inclusive. The instant claims include the positively recited elements of the device and any other elements not specifically recited such as those recite in the claims of the patent and encompass the inventions of claims 1-33 of the patent. The instant application is not associated with an administrative delay which would have prevented applicants from obtaining a patent on the instant claims. As a result, issuance of the instant claims would provide an unjustified timewise extension the patented claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is (703) 308-4006. The examiner can normally be reached on 6:40 AM to 4:10 PM, alternate Mondays off..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7718 for regular communications and (703) 305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

William H. Beisner
Primary Examiner
Art Unit 1744

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January 18, 2000